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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,182	05/05/2004	Michael D. Cleary	STAN-304	7494
24353	7590	08/14/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			PANDE, SUCHIRA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/840,182

Applicant(s)

CLEARY ET AL.

Examiner

Suchira Pande

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-37, drawn to a method (process) of labeling RNA, classified in class 435, subclass 6 for example.
 - II. Claims 38-41, drawn to a kit (product) for labeling RNA, classified in class 435, subclass 810 for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product (kit) can be used in many different ways. For example, purine or pyrimidine analogs can be used as drugs that inhibit viral replication. Therefore the inventions of group I and II are distinct. In addition a search for components of the kit (product) of invention II will not provide any information about the specific method steps of invention I. Hence searching for the two inventions is not coextensive.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. This application contains claims directed to the following patentably distinct species:

A. Species of purine or pyrimidine analog (claim 1 is generic)

- a. a uracil analog. (claim 5)
- b. a nitrogenous base. (claim 31)
- c. a nucleoside. (claim 32)

B. Species of tags (claim 1 is generic)

- d. a small molecule binding partner. (claim 6)
- e. biotin. (claim 7)
- f. a detectable label. (claim 8)
- g. tag is bound to a specific binding partner. (claim 10)
- h. tag is bound to a specific binding partner conjugated to an insoluble substrate for affinity chromatography. (claim 11)
- i. tag is bound to a specific binding partner conjugated to a detectable label. (claims 18 & 19)

C. Species of Methods for processing separated RNA (claim 11 is generic)

- j. RNA is reverse transcribed. (claim 12)
- k. RNA is amplified. (claim 13)

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- l. RNA is labeled with a detectable label. (claim 14)
- m. RNA is labeled by end-labeling. (claim 15)
- n. RNA is labeled by reverse transcriptase. (claim 16)
- o. RNA is labeled during amplification. (claim 17)
- p. RNA is cross-linked to an interacting molecule. (claim 22)

D. Species of Promoters (claim 2 is generic)

- q. promoter is constitutively active in said cell of interest (claim 23).
- r. promoter is inducible (claim 24).
- s. promoter is induced by the presence of a signaling molecule (claim 25)
- t. promoter is tissue specific (claim 26)
- u. promoter is cell type-specific (claim 27)

E. Species of vectors

- v. a replicable vector (claim 28).
- w. a virus (claim 29).
- x. an integrating vector (claim 30).

5. The species are independent or distinct because the purine or pyrimidine analogs enumerated in Group A above all are chemically distinct molecules. An analog of uracil for instance has structure that is different from nitrogenous bases such as adenine, cytosine and guanine and nucleosides.

The tags enumerated in Group B above are structurally different. For instance, the detectable label can be p32, which is radioisotope while biotin is a small molecule. In addition totally different biochemical procedures are used to label RNA with radioisotope or biotin. Hence tags enumerated in Group B are distinct.

Each of the methods claimed for processing RNA enumerated in Group C above is a different biochemical reaction recognized in the art as such. Hence methods of processing separated RNA are distinct.

The promoters claimed in Group D fall in different categories by definition. For example inducible promoter has different structure and mode of regulation than a constitutive promoter. Each of the promoters consists of unique nucleotide sequences and is thereby patentably distinct.

The vectors enumerated in Group E above are distinct. A replicable vector can be a plasmid having an origin of replication, which is distinct from a virus, which in turn is distinct from a vector that integrates into the host genome.

6. Applicant is required under 35 U.S.C. 121 to elect a one **disclosed species from each of the categories A-E**. That is applicant must elect one species from a-c for category A; one species from d-i for category B; one species from j-p for category C; one species from q-u for category D; and one species from v-x for category E prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

TERESA E. STRZELECKA, PH.D.
PRIMARY EXAMINER

Teresa Strzelecka
8/4/06